

**UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
SOUTHERN DIVISION**

STEPHANIE BAIN
20440 Raceground Rd.
Callaway, MD 20620

Plaintiff,

v.

ORGANON USA, INC.
56 Livingston Ave.
Roseland, NJ 07068

SERVE ON:
The Corporation Trust Co.
820 Bear Tavern Rd.
West Trenton, NJ 08628

and

N.V. ORGANON
One Merck Dr.
Whitehouse Station, NJ 08889

SERVE ON:
The Corporation Trust Co.
820 Bear Tavern Rd.
West Trenton, NJ 08628

and

SCHERING CORPORATION
2000 Galloping Hill Rd.
Kenilworth, NJ 07033

SERVE ON:
The Corporation Trust Co.
820 Bear Tavern Rd.
West Trenton, NJ 08628

and

MERCK & CO., INC.
One Merck Dr.
Whitehouse Station, NJ 08889

Case No.

**COMPLAINT AND
JURY DEMAND**

SERVE ON:)
The Corporation Trust Co.)
820 Bear Tavern Rd.)
West Trenton, NJ 08628)
)
and)
)
MERCK SHARP & DOHME)
CORPORATION)
One Merck Dr.)
Whitehouse Station, NJ 08889)
)
)
SERVE ON:)
The Corporation Trust Co.)
820 Bear Tavern Rd.)
West Trenton, NJ 08628)
)
Defendants.

COMPLAINT

COMES NOW Plaintiff Stephanie Bain (hereinafter “Plaintiff”), by and through undersigned counsel, and for her Complaint against Organon USA, Inc., N.V. Organon, Schering Corporation, Merck & Co., and Merck Sharp and Dohme, Corp. states as follows:

PARTIES AND JURISDICTION

1. Plaintiff is a resident and citizen of Mechanicsville, Maryland, located in St. Mary’s County.

2. Defendant Organon USA, Inc. is a New Jersey corporation with its principal place of business at 56 Livingston Ave., Roseland, New Jersey 07068. Defendant Organon USA, Inc. is a sales unit of the healthcare group of Akzo Nobel NV and Organon International, Inc. At all times relevant, Organon USA, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing,

and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug, NuvaRing®. At relevant times, Defendant Organon USA, Inc. conducted regular and sustained business in Maryland by selling and distributing its products in Maryland and engaged in substantial commerce and business activity in Maryland .

3. Defendant N.V. Organon is a foreign corporation with a principal place of business at Molenstraat 110, 5342 OCC Oss in the Netherlands. Defendant N.V. Organon conducted research and contributed to the development, the design, testing and manufacturer, as well as marketing and distribution of NuvaRing in the United States. Defendant N.V. Organon conducted regular and sustained business in Maryland by selling and distributing its products in Maryland and engaged in substantial commerce and business activity in Maryland.

4. Defendant Schering Corporation (herein after “Defendant Schering”) is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Defendant Schering conducted regular and sustained business in Maryland by selling and distributing its products in Maryland and engaged in substantial commerce and business activity in Maryland.

5. Defendant Schering acquired Organon BioSciences NV (OBS), in November 2007 and assumed the liabilities attendant thereto, including the liabilities of Defendant Organon USA, Inc. Organon BioSciences, NV, is comprised of Organon, a human health business (which includes Organon USA, Inc.), Intervet, an animal health business, Nobilon, a human vaccine development unit, and Diosynth, a third party manufacturing arm of Organon.

6. In 2008, Defendant Schering acquired Organon Pharmaceuticals USA, Inc., and caused it to be dissolved as a corporation; and made it a subsidiary. In so doing, Schering assumed the liabilities of Organon Pharmaceuticals USA, Inc. Upon information and believe, Organon Pharmaceuticals, Inc. was the United States pharmaceutical arm of Organon International, Inc. Until dissolution Organon Pharmaceuticals USA, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, packaging, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug, NuvaRing®. Upon information and belief, Organon Pharmaceuticals USA, Inc. was at all times relevant to this Complaint part of the Akzo Nobel, NV business unit of Organon.

7. Defendant Schering expressly and/or impliedly assumed the liabilities and obligations of Organon USA, Inc. and Organon International, Inc., including the injuries and damages associated with NuvaRing® and alleged herein.

8. Hereinafter, Defendants Organon USA, Inc., N.V. Organon and Schering Corporation will be referred to collectively as “Organon” or “Organon Defendants”.

9. In or about November 2009, Defendant Merck & Co., Inc., completed the merger with Schering Corporation, which included Organon and the liabilities and assets associated with NuvaRing. Defendant Merck & Co., Inc. is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, NJ, 08889-0100. Defendant Merck Sharp & Dohme is a New Jersey corporation organized, existing and conducting business in the State of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, NJ, 08889-0100. Defendants Merck & Co., Inc.

and Merck Sharp & Dohme conducted regular and sustained business in Maryland by selling and distributing its products in Maryland and engaged in substantial commerce and business activity in Maryland.

10. In the merger, Schering Corporation acquired all of the shares of Merck & Co., Inc., which became a wholly-owned subsidiary of Schering-Plough Corporation and was renamed Merck Sharp & Dohme Corp. Schering continued as the surviving public company and was renamed Merck & Co., Inc.

11. Upon information and belief, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. expressly and/or impliedly assumed the liabilities and obligations of Schering-Plough and the named Organon defendants for the injuries and damages alleged herein resulting from Plaintiff's use of NuvaRing.

12. Upon information and belief, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. have continued the business and operation of Schering-Plough Corporation and the named Organon Defendants, including, but not necessarily limited to the NuvaRing.

13. Therefore, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. are liable to Plaintiff for the injuries and damages alleged herein as a successor in interest and/or successor corporations of Schering-Plough Corporation and the Organon defendants named herein.

14. This court has personal jurisdiction over the defendants in that the prescription drug at issue, NuvaRing®, was marketed, sold, or otherwise distributed within the State of Maryland.

15. This court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties and the amount in controversy exceeds \$75,000.00 exclusive of interest and costs.

16. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district, as the Plaintiff was injured within the District of Maryland (Southern Division) and Defendants collectively have marketed, sold, or otherwise distributed NuvaRing® within the District of Maryland (Southern Division).

TAG-ALONG ACTION

17. This is a potential tag-along action and in accordance with 28 U.S.C. §1407, it should be transferred to the United States District Court for the Eastern District of Missouri for inclusion in *In re: NuvaRing® Products Liability Litigation*, MDL 1964, Case No. 08-md-1964 (Hon. Rodney W. Sippel).

FACTUAL BACKGROUND

18. Upon information and belief, upon the merger of Defendant Merck and Defendant Schering into Defendant Corporation Sharp & Dohme, Corp., Defendants Merck & Co., Inc. and Defendant Merck Sharp & Dohme, Corp. assumed the liabilities and obligations of Defendants Organon associated with NuvaRing®, including the liabilities associated with the damages and injuries alleged herein by Plaintiff. Therefore, all named Defendants are liable to Plaintiff who was injured due to her use of the said NuvaRing® product, either by virtue of being the corporation which engages in the conduct stated above, or as successor corporations having assumed the liability through the purchase of a predecessor corporation.

19. Defendants market NuvaRing® as the first and only, once-a-month vaginal birth control ring, and further markets NuvaRing® as providing the same efficacy as birth control pills or the patch in preventing pregnancy, but with more convenience because it offers “month-long protection against pregnancy, so women who use NuvaRing don't have to think about contraception every day.”

20. At all times material hereto, Defendants failed to properly disclose the known safety hazards associated with NuvaRing®.

21. The package insert accompanying NuvaRing® stated that the vaginal ring is expected to be associated with similar risks to that of birth control pills and that the safety information they provide to consumers is derived primarily from studies of birth control pills.

22. Therefore, the safety information provided to the consumer was not derived primarily from studies of NuvaRing® and, therefore, the package insert accompanying NuvaRing is misleading.

23. Defendants, including by and through their predecessor and affiliate corporations, failed to warn of the extent of the risk of venous thromboembolism, including Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), and death associated with use of the novel combined contraceptive vaginal route of administration, the NuvaRing®.

24. Etonogestrel, a synthetic, third-generation progestin, that Defendants use in the NuvaRing® as a starting agent, was not the subject of sufficient and adequate testing, and Defendants knew or should have known that information conveying

potential adverse events involving DVT, PE, and death should be set forth in the package insert.

25. Defendants knew, but failed to disclose that the NuvaRing® had a higher risk of thromboembolic complications than the pill, due to the markedly potentiated androgenic effects caused by the synthetic, third-generation progestin used in the NuvaRing®.

26. Defendants negligently and/or recklessly marketed the NuvaRing® as a novel vaginal delivery system, and placed the product into the stream of commerce without conducting adequate tests to regulate the exposure and/or release rates of estrogen and Progestin to a user, including Plaintiff, of such product.

27. At all times material hereto, Defendants, by and through their agents, servants and/or employees, negligently, recklessly, carelessly and/or grossly negligently marketed, distributed and/or sold NuvaRing® without adequate instructions or warnings of its known serious side effects and unreasonably dangerous risks.

28. Instead, Defendants market NuvaRing® as having a low risk of side effects and continues to minimize NuvaRing®'s side effects by focusing on the incidence of minor side effects, stating, "With NuvaRing® there is a low incidence of side effects, such as headaches, nausea, and breast tenderness."

29. As a result of the claims of Defendants regarding the effectiveness and safety of NuvaRing, Plaintiff began using the NuvaRing® contraceptive in or about May 2012. While on the NuvaRing®, on or about November 20, 2012, at age eighteen (18), Plaintiff began to experience chest pain and shortness of breath.

30. As a result of her chest pain and shortness of breath, Plaintiff visited St. Mary's Hospital in Leonardtown, Maryland. A CT scan revealed a pulmonary embolism. Plaintiff was immediately placed on anticoagulation therapy, including Lovenox and Coumadin. Plaintiff was hospitalized for four (4) days. On or about November 23, 2012 Plaintiff was discharged from the hospital with instructions to remain on Coumadin therapy and to discontinue the use of NuvaRing®.

31. As a direct and proximate result of using the NuvaRing®, Plaintiff suffered injuries and continues with regular follow-up care, including but not limited to, examinations, appointments and medications.

32. Prior to Plaintiff's use of NuvaRing®, Defendants knew or should have known that use of their products created a higher risk of venous thromboembolism than oral contraceptives.

33. Despite the fact that Defendants knew or should have known of the serious health risks, including venous thromboembolism associated with the use of the NuvaRing® particularly to Plaintiff, Defendants failed to warn Plaintiff of said serious risks before she used the product and failed to conduct appropriate testing prior to the NuvaRing being prescribed to Plaintiff.

34. Had Plaintiff known the risks and dangers associated with NuvaRing®, she would not have used NuvaRing and would not have suffered the aforementioned injuries.

35. As a direct and proximate result of Plaintiff's use of NuvaRing®, Plaintiff suffered intense and excruciating physical pain and suffering from the initial onset of her

injuries until she ultimately required hospitalization, including but not limited to the fact that she experienced pain and swelling.

36. Further, as a direct and proximate result of Plaintiff's use of NuvaRing®, Plaintiff has suffered economic and non-economic losses, has incurred hospital expenses and expenses related to follow up care.

37. Defendants' actions and omissions as identified in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of damages based on aggravating circumstances.

COUNT I

Strict Products Liability--Defective Manufacturing As to Organon Defendants

38. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

39. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of NuvaRing® and were responsible for marketing, labeling, and/or selling the NuvaRing® and otherwise putting it into the stream of commerce.

40. The NuvaRing® manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications, rendering it unreasonably dangerous and thereby posing a serious risk of injury and death to consumers, including Plaintiff.

41. As a direct and proximate result of using Defendants' unreasonably dangerous product, Plaintiff sustained injuries as described herein. As a result, Plaintiff

suffers economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

42. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from the initial onset of her injuries until the time of her pulmonary embolism, incurring substantial medical and other expenses as a result.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

COUNT II

Strict Products Liability – Defective Design As to Organon Defendants

43. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

44. Defendants were the manufacturers, designers, distributors, sellers, or suppliers of NuvaRing and were responsible for marketing, labeling, and/or selling the NuvaRing and otherwise putting it into the stream of commerce.

45. The NuvaRing manufactured and supplied by Defendants contained an unreasonably dangerous defect in design or formulation in that, when it left the hands of Defendants, an average consumer could not reasonably anticipate the dangerous nature of the NuvaRing® nor fully appreciate the attendant risk of injury associated with using the NuvaRing®.

46. NuvaRing® was defective in that it was not properly designed or prepared and/or was not accompanied by proper warnings regarding the prevalence and severity of adverse side effects associated with its use.

47. NuvaRing® was further defective in that its design and manufacture contained unnecessarily dangerous hormones and released uneven amount of the said hormones.

48. The foreseeable risks associated with the design of the NuvaRing® include, but are not limited to, the fact that NuvaRing® is more dangerous and presents a greater risk of injury than an ordinary consumer would reasonably expect when using this type of product in an intended or reasonably foreseeable manner.

49. At the time the NuvaRing® left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, including use of a second generation progestin, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

50. As a direct and proximate result of using Defendants' unreasonably dangerous product, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

51. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating

pain and suffering from her injuries, incurring substantial medical and other expenses as a result.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

COUNT III

Strict Products Liability -- Defect Due to Inadequate Warning As to Organon Defendants

52. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

53. The NuvaRing® manufactured and supplied by Defendants was unreasonably dangerous due to inadequate warning or instruction because Defendants knew or should have known that the product created hidden risks of serious bodily harm and death and they failed to adequately warn Plaintiff and/or her health care providers of the extent of such risks, including the extent of risk of the types of injuries Plaintiff suffered as a result of using the NuvaRing®.

54. Defendants marketed, promoted and advertised their NuvaRing® product to physicians and to the public as more effective and safe than the oral contraceptive pill, at a time that the Defendants had actual and/or constructive knowledge that the NuvaRing was less safe than the pill.

55. Defendants failed to warn prescribing physicians and the public that the NuvaRing® was associated with increased risk of cardiovascular thromboembolic complications than the pill.

56. Defendants knew, but failed to disclose that NuvaRing had a higher risk of cardiovascular thromboembolic complications than the pill, due to the markedly potentiated androgenic effects caused by the synthetic progestin used in the NuvaRing.

57. Defendants failed to provide proper and full information as to the safety of the NuvaRing to the U.S. Food and Drug Administration, which regulates the sale of the NuvaRing.

58. Defendants did not reasonably warn the medical profession of precautions and known potential complications of NuvaRing® to enable physicians and other healthcare providers to reasonably assess the risks versus the benefits of the use of the NuvaRing® for contraception.

59. Defendants failed to adequately warn prescribing physicians, pharmacists, and users of the NuvaRing® of the refrigerated storage requirements.

60. Plaintiff and her prescribing physician were unaware of the increased risks and danger of harm inherent in NuvaRing®, as above described, and would have used and prescribed other methods for birth control if they had been so informed.

61. Defendants' failure to warn of the increased risks and danger of harm inherent in NuvaRing®, as described above, created an unreasonable danger to users of this product, and the product was unreasonably dangerous at the time it was prescribed to Plaintiff.

62. Plaintiff was prescribed and used the NuvaRing® for its intended purpose and as reasonably anticipated without knowledge of its characteristics, and could not have discovered any defect in the product through the exercise of reasonable care.

63. The warnings that were given by Defendants were not accurate, clear and/or were ambiguous.

64. As a direct and proximate result of Defendants' inadequate warnings regarding the safety of NuvaRing®, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

65. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

COUNT IV

Breach of Express Warranty As to Organon Defendants

66. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

67. Defendants expressly warranted that NuvaRing was a safe and effective prescription contraceptive.

68. Defendants promoted NuvaRing® to the FDA, prescribing doctors, the public and Plaintiff, as "safe," "favorable safety profile," "low side effects," "less side effects," "low hormones" and other similar terms.

69. Defendants deliberately promoted what it called “low estrogen” in its said product as a means of avoiding reference to the dangerous progestin which it used in the product, and used the dangerous progestin as compared to other, safer progestins to save money since they owned the patent to the progestin which they used.

70. Members of the consuming public, including Plaintiff, were intended beneficiaries of the warranty.

71. The NuvaRing® manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.

72. Defendants breached their express warranty in one of more of the following ways:

- a) NuvaRing®, as designed, innovated, marketed, manufactured, and/or sold and distributed by Defendants, was defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition.
- b) Defendants failed to warn of the likelihood and severity of adverse side effects of NuvaRing®, and/or did not provide adequate warnings and instructions on the product, nor did they employ other reasonable means to inform doctors and patients of the risks of the drug.
- c) Defendants failed to adequately test NuvaRing® and to monitor its effects.
- d) Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the true risks of injury from NuvaRing®.

73. As a direct and proximate result of Defendants’ breach of warranty, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

74. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, Individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

COUNT V

Breach of Implied Warranty As to Organon Defendants

75. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

76. At the time Defendants designed, manufactured, marketed, sold, and distributed NuvaRing for use by Plaintiff, Defendants knew of the use for which NuvaRing® was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

77. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether NuvaRing® was of merchantable quality and safe for its intended use and upon the Defendants' implied warranty as to such matters.

78. Contrary to such implied warranty, NuvaRing® was not of merchantable quality or safe for its intended use, because the product was unreasonably dangerous as described above.

79. As a direct and proximate result of Defendants' breach of warranty, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

80. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

COUNT VI

Strict Products Liability Defect Due to Nonconformance with Representations As to Organon Defendants

81. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

82. Defendants made representations regarding the safety of NuvaRing®.

83. The representations that Defendants made regarding the safety of NuvaRing were made on Defendants' knowledge, or under circumstances in which Defendants necessarily ought to have known the truth or untruth of the representations.

84. The NuvaRing® supplied by Defendants was defective in that it did not conform to representations made by Defendants concerning the safety of the product.

85. Defendants had an economic interest in all transactions involving sales and prescriptions of NuvaRing®.

86. Plaintiff justifiably relied upon all Defendants' representations regarding NuvaRing when she used it.

87. As a direct and proximate result of Defendants' misrepresentations regarding the safety of NuvaRing®, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

88. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

COUNT VII

Strict Products Liability Defect Due to Failure to Adequately Test As to Organon Defendants

89. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

90. Defendants repeatedly advised consumers and the medical community that NuvaRing® contained the same safety profile as oral hormonal birth control pills.

Defendants failed to adequately test the safety of NuvaRing versus oral hormonal birth control pills.

91. Had Defendants adequately tested the safety of NuvaRing® versus oral hormonal birth control pills and disclosed those results to the medical community or the public, Plaintiff would not have undertaken birth control therapy with NuvaRing®.

92. As a direct and proximate result of Defendants' failure to adequately test the safety of NuvaRing® versus oral hormonal birth control pills, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

93. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

COUNT VIII

Negligence As to Organon Defendants

94. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

95. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of NuvaRing® into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

96. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of NuvaRing® into interstate commerce in that Defendants knew, or should have known, that the product caused such significant bodily harm or death and was not safe for use by consumers.

97. Defendants failed to exercise ordinary care in the labeling of NuvaRing® and failed to issue to consumers and/or their health care provider's adequate warnings of the risk of serious bodily injury or death due to the use of the NuvaRing®.

98. Despite the fact that Defendants knew or should have known that NuvaRing® posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market NuvaRing for use by consumers.

99. Defendants knew or should have known that consumers, including Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

100. Defendants deliberately bypassed confining its promotion of NuvaRing® to learned intermediaries and instead engaged in extensive and expensive direct-to-consumer advertising, including over the internet, in which promotional material adequate warnings were not given, thereby assumed a direct duty to the user.

101. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the negligence of Defendants as follows:

- a) In its failure to warn or instruct, and/or adequately warn or adequately instruct, users of NuvaRing®, including Plaintiff, of its known dangerous and defective characteristics;
- b) In its design, development, implementation, administration, supervision and/or monitoring of clinical trials for NuvaRing®;
- c) In its promotion of NuvaRing® in an overly aggressive, deceitful and fraudulent manner, despite knowledge of the product's defective and dangerous characteristics due to its propensity to cause serious injury and/or death;
- e) In representing that NuvaRing® was safe for its intended use when, in fact, the product was unsafe for its intended use;
- f) In utilizing dangerous levels of progestins which was never used before as a starting agent in contraceptives and without first conducting adequate testing;
- g) In utilizing combined contraceptives in a vaginal route of administration without first conducting adequate testing as to the release and/or exposure rates of such contraceptives;
- h) In failing to perform appropriate pre-market testing of NuvaRing®;
- i) In failing to perform appropriate post-market testing of NuvaRing®;
- j) In failing to perform appropriate post-market surveillance of NuvaRing®;

- k) In failing to properly ship, transport, and deliver NuvaRing® in the required refrigerated storage;
- l) In failing to adequately instruct its employees and/or agents and medical professionals of the necessity to store NuvaRing® in refrigerated containers; and
- m) In failing to have uniform labels on contraindications of use of the product.

102. As a direct and proximate result of Defendants' negligence, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

103. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

COUNT IX

Intentional and/or Negligent Misrepresentation As to Organon Defendants

104. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

105. Defendants knew or were aware or should have been aware that NuvaRing® had not been sufficiently tested, and was unsafe, defective in design and manufacture, unreasonably dangerous and/or that it lacked adequate and/or sufficient warnings.

106. Defendants knew and were aware or should have been aware that NuvaRing® promoted more risks of clotting than other contraceptives demonstrating that further testing was needed.

107. Defendants knew or should have known that NuvaRing® had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

108. Defendants knew or should have known the safety profile in the U.S. label was misleading to prescribing doctors and users of NuvaRing®, including Plaintiff, as the label contained contraindications different than that of other NuvaRing labels.

109. Plaintiff reasonably relied upon Defendants' representations to Plaintiff and/or her health care providers that NuvaRing® was safe for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

110. As a direct and proximate result of Defendants' fraudulent and/or negligent actions and omissions, Plaintiff used NuvaRing® and sustained injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss,

and damages for aggravating circumstances and other losses in an amount to be proven at trial.

111. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

COUNT X

Violation of the Maryland Consumer Protection Act As to Organon Defendants

112. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

113. At all times relevant, the Maryland Consumer Protection Act, section 13-301 et seq. (hereinafter "the Act"), prohibits "unfair or deceptive trade practice in the sale or offer for sale of any consumer goods or consumer services," and declares such acts or practices as unlawful.

114. Defendants violated the Act by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of NuvaRing. Defendants communicated the purported benefits of NuvaRing while failing to disclose the serious and dangerous side effects related to the

use of NuvaRing with the intent that consumers, like Plaintiff, and her healthcare providers would rely upon the misrepresentations and purchase or prescribe NuvaRing.

115. As a result of violating the Act, Defendants caused Plaintiff to be prescribed and to use NuvaRing, causing injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

116. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of the Defendants, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

COUNT XI

Successor Liability

As to Defendants Merck & Co., Inc., and Merck Sharp & Dohme Corp.

117. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

118. In or about November 2009, Defendant Merck & Co., Inc., completed the Merger with Schering-Plough Corporation, which included Organon and the liabilities and assets associated with NuvaRing®.

119. In the Merger, Schering-Plough Corporation acquired all of the shares of Merck & Co., Inc., which became a wholly-owned subsidiary of Schering-Plough

Corporation and was renamed Merck Sharp & Dohme Corp. Schering-Plough continued as the surviving public company and was renamed Merck & Co., Inc.

120. Upon information and belief, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. expressly and/or impliedly assumed the liabilities and obligations of Schering-Plough and the named Organon defendants for the injuries and damages alleged herein resulting from Plaintiff's use of NuvaRing®.

121. Upon information and belief, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. have continued the business and operation of Schering-Plough Corporation and the named Organon Defendants, including, but not necessarily limited to NuvaRing®.

122. Therefore, Defendant Merck & Co., Inc. and Merck Sharp & Dohme Corp. is liable to Plaintiff for the injuries and damages alleged herein as a successor in interest and/or successor corporations of Schering-Plough Corporation and the Organon defendants named herein.

WHEREFORE, Plaintiff demands Judgment on this Count against Defendants, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, for the foregoing reasons, Plaintiff prays for relief as follows:

1. Damages against all defendants in excess of \$75,000.00, and in an amount that is fair and just to compensate Plaintiff for the damages she has suffered and will continue to suffer as a result of Plaintiff injuries including, without limitation, economic loss, non-economic loss, and all other damages.

2. Damages due to the aggravating circumstances attending Plaintiff injuries;

3. Damages against all defendants based on the intense pain and suffering that Plaintiff endured from the initial onset of her injuries and continued follow up appointments, and for the substantial medical and other expenses that she incurred as a result;

4. Attorneys' fees, expenses, and costs of this action; and

5. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Respectfully submitted,

/s/ Elisha N. Hawk

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